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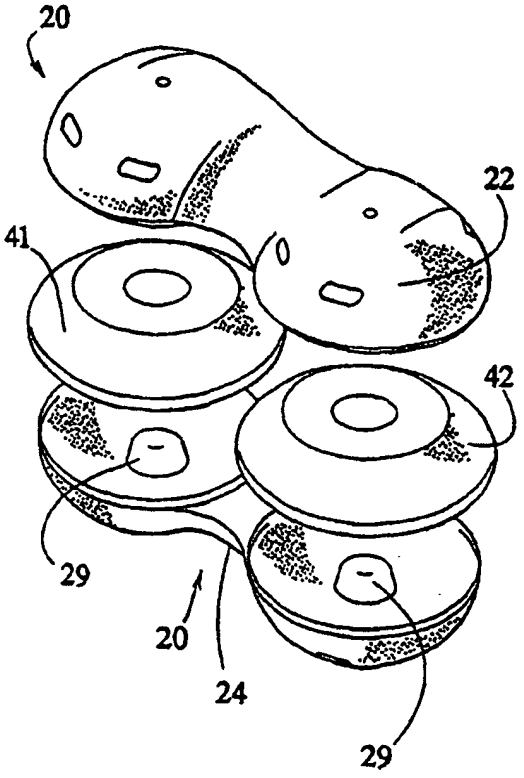
(54) Title: PEANUT SPECTACLE MULTI DISCOID THORACO-LUMBAR DISC PROSTHESIS

(57) Abstract

A small profile, peanut spectacle-shaped prosthetic disc device (20) is provided. The device housing is comprised of two longitudinally split hollow halves (22, 24), between which are contained multiple discoid shaped resilient bodies (41, 42) which may be of a polymeric type, or they may contain hydrogel. These bodies may lie in concave surfaces (51, 52) located on the interior of each side of the split cylindrical housing. The housing halves, even under maximum physiological loads, do not contact one another directly. The shell shape permits relatively easy introduction of the intervertebral spaces in the thoracic or lumbar region of the human spine.



PEANUT SPECTACLE MULTI DISCOID THORACO-LUMBAR DISC PROSTHESIS

This invention relates to the design and use of a unique disc prosthesis for the lumbar and thoracic spine. By placing one or more ovoid resilient prosthetic nuclei in series inside a peanut-shaped housing of metal ceramic or polymeric material, which housing is shaped so that it is separated into two sections longitudinally, a thin profile prosthesis can be created which will allow placement of the device through a small opening for implant into the thoracic or lumbar portion of the spine.

U.S. Patent 5,674,296 is incorporated by reference.

Degenerative disc disease, including disc herniation, may produce disabling symptoms of local pain, radiculopathy or myelopathy in an otherwise clinically stable spine, and may be unresponsive to non-surgical treatment. Several surgical treatments are available to address the symptoms of degenerative disc disease when non-invasive therapies are not effective. These surgical treatments include decompression, discectomy and fusion. These treatments, and in particular the discectomy and fusion procedures, provide relief of clinical symptoms but they do not restore normal or near normal range of motion or cushioning to the affected functional spinal unit (FSU). This can result in acceleration of the degenerative process in spinal discs adjacent to the original surgical operation site. This degenerative process can, in turn, require additional surgical intervention.

Open surgery and endoscopic techniques are often used to provide access to the targeted intervertebral disc space. Posterior, postero-lateral, and anterior approaches allow placement of instrumentation to facilitate exposure of the degenerated disc and the insertion of bone grafts or fusion cages to accomplish bony fusion.

Because of anatomical structure considerations and instrument size restrictions associated with minimally invasive surgical techniques in the anterior lumbar spine, the insertion of a functional disc prosthesis equal in size to the natural disc creates

risks due to mechanical interferences with critical vascular structures.

A functional disc prosthesis which provides for a full range of motion of the FSU and for cushioning between two adjacent vertebrae while maintaining stability, intervertebral body spacing and lordosis, is desirable.

One aspect of the invention provides a disc prosthesis comprising a peanut shaped housing, the housing including an upper half and a lower half and a plurality of resilient, viscoelastic discs interposed between the upper half housing and the lower half housing to maintain the housing halves separate from one another.

Another aspect of the invention provides a disc prosthesis affixed within a human spine, the prosthesis comprising a peanut shaped upper half housing engaging the cephalad vertebral bone inferior end plate and cancellous bone; a peanut shaped lower half housing engaging the caudal vertebral bone superior end plate and cancellous bone; and a plurality of separate, resilient discs interposed between the housing halves.

A further aspect of the invention provides a plurality of disc prostheses located within a human spine, each prosthesis comprising an upper half housing engaging a cephalad bone inferior end plate and cancellous bone; a lower half housing engaging a caudal vertebral bone superior end plate and cancellous bone; and resilient material interposed between the housing halves.

Yet another aspect of the invention provides a viscoelastic prosthetic disc for use in a human spinal implant, the disc having viscoelastic properties, the prosthetic disc having convex external surfaces for sliding engagement with concave surfaces formed on the interior of rigid upper and lower half housings.

Yet a further aspect of the invention provides a disc prosthesis comprising a housing, the housing having an exterior surface defining a pair of lobed formations, the housing including at least two rigid, confronting and complimentary parts, the prosthesis further comprising at least one resilient, viscoelectric disc interposed between the housing parts to maintain the housing parts separate from one another but to provide cushioning between the housing parts and to permit limited motion from between the housing parts.

Each housing half is separated from the other at all times by disk shaped resilient bodies contained therein, and is strong enough to support the loads to which it shall be

subjected during the activities of daily living. The discoid nuclei are preferably of smaller diameter than the natural discs they replace, and are positioned in the shell concave interiors of the peanut shaped housing. The housing is preferably configured to accommodate the restrictions imposed by the limited anatomical space available for the surgical placement of the implant, and is preferably small so as to utilize implantation procedures and instrumentation such as those used in an endoscopic procedure.

It is an object of preferred embodiments of the invention to provide a disc prosthesis having a small or narrow profile.

It is a further object of preferred embodiments of the invention to provide geometry to engage concave mating surfaces on the vertebral bodies or bones so as to provide proper stability and proper positioning of the opposing engaged vertebrae or vertebral bodies.

Another object of preferred embodiments of the invention is to obviate the need for a second surgical site for bone graft harvesting as may be required when spinal fusion cages are implanted.

And it is a further object of preferred embodiments of the invention to provide a sheath so as to completely surrounded and enclose the space occupied by the resilient bodies between the two housing halves, thereby restricting the migration of debris outside the prosthesis, restricting cancellous tissue ingrowth into the device, and providing a sealed space around the prosthetic nucleus in which lubricant may be contained.

Still another object of preferred embodiments of the invention is to provide a disc prosthesis which will permit motion between the housing halves.

A further object of preferred embodiments of the invention is to provide a disc prosthesis which will provide for cushioning between the housing halves.

It is a still further object of preferred embodiments of the invention to provide a disc prosthesis which may be used alone or in parallel array with similar prostheses.

It is yet another object of preferred embodiments of the invention to provide a housing having one or more ports through which a liquid (for example, a saline fluid, hyaluronic acid, or similar lubricating fluid material including for example a hydrogel material) can be introduced into the housing interior space confined within the sheath and

and partly occupied by the disc for purposes of lubrication, spacing, and/or cushioning. A plug, screw or other can also be provided to seal closed the port following introduction of that material.

Other objects and advantages of preferred embodiments of the invention will become apparent to those skilled in the art upon reading the following detailed description of the preferred embodiments by way of example only, and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

Figure 1 is a top plan view of a spinal prosthesis according to a preferred embodiment of the invention.

Figure 2 is an end view of the prosthesis shown in figure 1.

Figure 3 is a sectional view taken substantially in the plane of line 3 – 3 in figure 1.

Figure 4 is an exploded view of the prosthesis of figure 1.

Figure 5 is a top plan view of the interior of one of the shelves comprising the prosthesis of figure 1.

Figure 6 is a side elevational view of the shell half shown in figure 5.

Figure 7 is an end view of the shell half shown in figures 5 and 6.

Figure 8 is a fragmentary view of the shell half shown in figure 7, but showing in further detail the half edge shape which is adapted to engage the implant sheath and a circlage wire.

Figure 9 is an exploded view showing the interiors of the shell halves.

While the invention will be described in connection with a preferred embodiment, it will be understood that it is not intended to limit the invention to this embodiment. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

To accomplish the objectives set out above, the disc prosthesis 10 according to a preferred embodiment of the invention includes, as shown in the drawings, a peanut shaped housing 20. The housing 20 includes an upper half housing 22 and a lower half housing 24.

As particularly shown in figures 2, 3, and 4, a plurality of resilient, viscoelastic discs 41, 42 are interposed between the upper half housing 22 and the lower half housing 24 to maintain the housing halves separate from one another and to provide for a defined range of motion between the housing halves and, consequently, for the implant patient's spine. Alternatively, the discs 41, 42 may be made of a suitable hydrogel. The discs can have a relatively soft and resilient interior and a relatively hard and durable exterior. If desired, generally conical bosses or posts 29 can fit into recesses 33 formed in the discs 41, 42 to provide stability and limitation against excessive motion. Also if desired, these posts 29 can be provided with small passageways 31 to permit the introduction of fluids or gel into the interior of the assembled implant. As shown in figure 3, circlage wires 37, 38 or other known devices can be fit into grooves 41 (figure 8) formed at the edge of the shell halves 22, 24 so as to attach and retained a fluid-retaining sheath 39, as suggested in U.S. Patent 5,674,296.

Ports 31 can be formed in the shell halves 22, 24 to permit lubricating fluids or gels to be introduced into the interior of the assembled implant. The ports 31 can later be sealed by a plug, a screw or the like if desired to prohibit the later expulsion or loss of the introduced fluid or gels. Recesses 47, 48 permit bone ingrowth and consequently firm, permanent attachment of the implant to the mating vertebral bone surfaces.

The prosthetic device 10 can be implanted in the thoracic or lumbar region of the spine through a small surgical opening. One device 20 containing two or more discs 41, 42 may be used, or by placing two such devices 20 in parallel, each containing two or more ovoid discs in series, a full range of motion of the functional spinal unit (FSU) can be achieved. If the discoid material possesses resilient, viscoelastic properties, with the housing being split with the internally placed ovoid discs maintaining the separation of the upper and lower housing members, a cushioning effect may also be realized.

As suggested in figures 5 and 9, each ovoid disc 41, 42 may be partly surrounded and retained by a concave surface 51, 52 formed or contained within the housing, and contoured to accept the upper and lower surface shape of each of the ovoid discs 41, 42 so that the housing 20 comprising the two or more halves or paired shells 23, 24 may slide and/or rotate over the surface of the discs 41, 42 to provide for joint space separation and motion.

The device may be inserted via open or minimally invasive techniques including endoscopy, or by a variety of known surgical anterior, posterior, lateral or other approaches where adequate anatomical space is available. Though the prosthesis is inserted as a single cylindrical unit, its final position is such that one half of the housing is left exclusively in contact with the cephalad vertebral bone with the caudal vertebral bone superior end plate. The discoid vertebral bodies between the cylindrical housing halves contain two or more concave surfaces, allow movement by providing for sliding and rotating in multiple directions and cushioning in response to physiological loads placed upon them.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A disc prosthesis comprising a peanut shaped housing, the housing including an upper half and a lower half and a plurality of resilient, viscoelastic discs interposed between the upper half housing and the lower half housing to maintain the housing halves separate from one another.

2. A disc prosthesis according to claim 1 wherein said discs are ovoid in shape.

3. A disc prosthesis according to claim 1 wherein each disc is partly surrounded by a concave surface formed within said housing.

4. A disc prosthesis affixed within a human spine, the prosthesis comprising a peanut shaped upper half housing engaging the cephalad vertebral bone inferior end plate and cancellous bone; a peanut shaped lower half housing engaging the caudal vertebral bone superior end plate and cancellous bone; and a plurality of separate, resilient discs interposed between the housing halves.

5. A disc prosthesis according to claim 4 wherein each disc is partly surrounded by a concave surface formed within one of said housing halves.

6. A disc prosthesis according to claim 1 in which each housing half is at least partly defined, in its interior, by a concave surface.

7. A plurality of disc prostheses located within a human spine , each prosthesis comprising an upper half housing engaging a cephalad bone inferior end plate and cancellous bone; a lower half housing engaging a caudal vertebral bone superior end plate and cancellous bone; and resilient material interposed between the housing halves.

8. A plurality of disc prostheses according to claim 7 wherein the prosthesis shell has recesses defined in its exterior surface to permit bone ingrowth.

9. A viscoelastic prosthetic disc for use in a human spinal implant, the disc having viscoelastic properties, the prosthetic disc having convex external surfaces for sliding engagement with concave surfaces formed on the interior of rigid upper and lower half housings

10. The disc of claim 9 wherein said disc has a relatively soft and resilient interior and a relatively hard and durable exterior.

11. A disc prosthesis comprising a housing, the housing having an exterior surface defining a pair of lobed formations, the housing

including at least two rigid, confronting and complimentary parts, the prosthesis further comprising at least one resilient, viscoelectric disc interposed between the housing parts to maintain the housing parts separate from one another but to provide cushioning between the housing parts and to permit limited motion from between the housing parts.

12. A disc prosthesis according to claim 11 including a sheath attached to said housing halves.

13. A disc prosthesis according to claim 11 in which a sealable portal is defined in said housing, the portal defining a passageway through which a lubricant or irrigant can be introduced into space between the nucleus and the housing interior surface.

14. A disc prosthesis, substantially as described with reference to the drawings.

DATED this 13th day of June, 2001

Spinal Dynamics Corporation

by DAVIES COLLISON CAVE
Patent Attorneys for the Applicants

FIG. 4

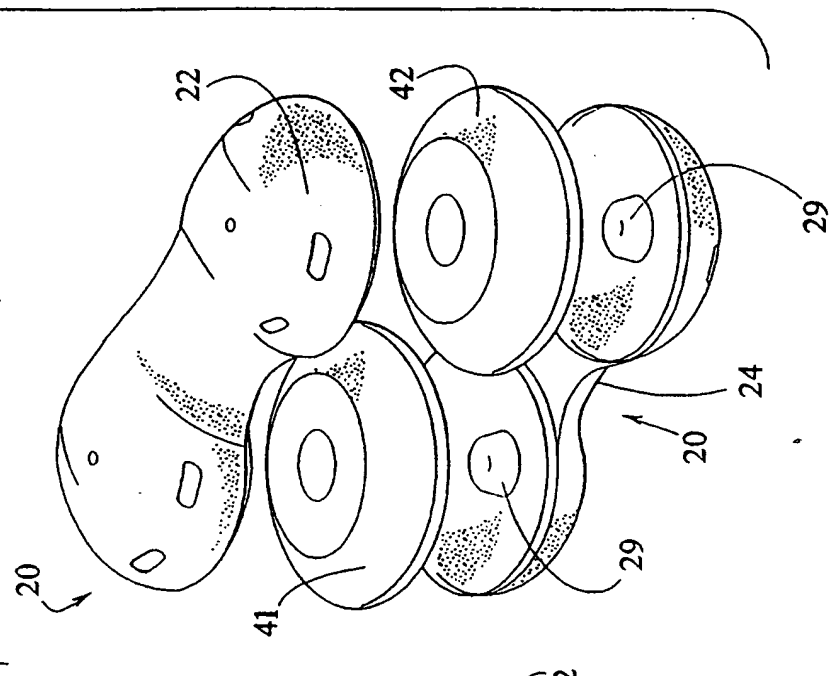


FIG. 2

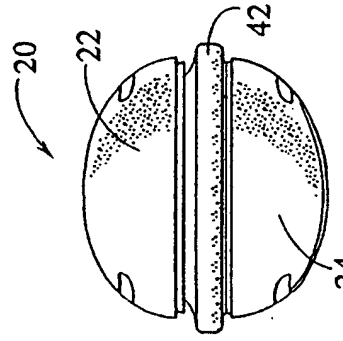


FIG. 1

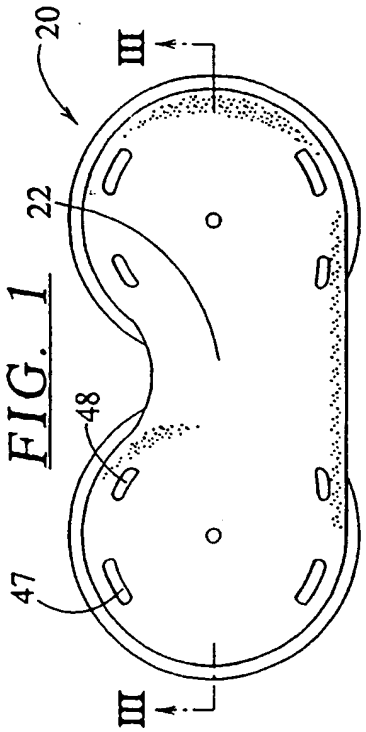
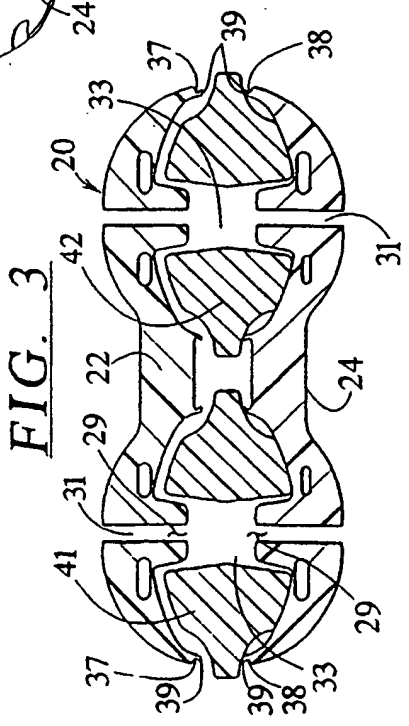


FIG. 3



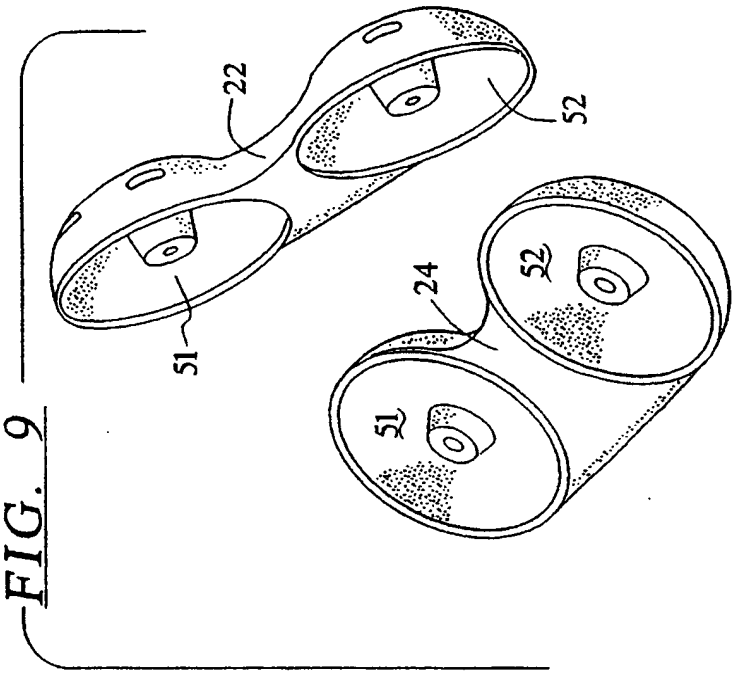


FIG. 9

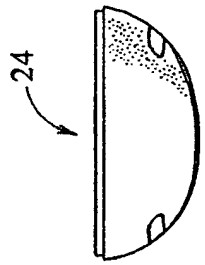


FIG. 7

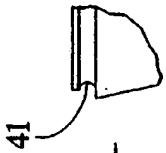


FIG. 8

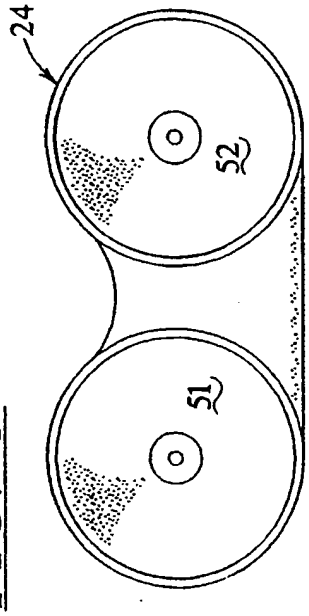


FIG. 5

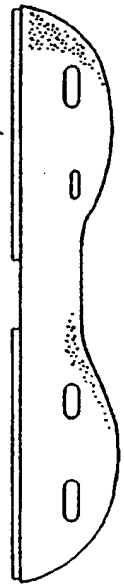


FIG. 6